

## § 70.11

application proposes, for coloring purposes only, the inclusion of a color additive, the provisions of the regulations in part 71 of this chapter shall apply with respect to the information that must be submitted about the safety of the color additive, if such information has not previously been submitted and safety of the color additive for the intended use has not already been established.

(2) If an application for a new drug inferentially contains a proposal for a color additive regulation, and the applicant fails to designate it as such, the Commissioner, upon determining that the application includes a proposal for a color additive regulation, shall so notify the applicant and shall thereafter proceed in accordance with the regulations in part 71 of this chapter.

(3) Where a petition for a color additive must be filed in accordance with paragraph (b)(2) of this section, the date of filing of the color additive petition shall be considered as the date of filing of the new-drug application.

[42 FR 15636, Mar. 22, 1977, as amended at 64 FR 400, Jan. 5, 1999]

### § 70.11 Related substances.

(a) Different color additives may cause similar or related pharmacological or biological effects, and, in the absence of evidence to the contrary, those that do so will be considered to have additive toxic effects.

(b) Food additives may also cause pharmacological or biological effects similar or related to such effects caused by color additives, and, in the absence of evidence to the contrary, those that do so will be considered as having additive toxic effects.

(c) Pesticide chemicals may also cause pharmacological or biological effects similar or related to such effects caused by color additives, and, in the absence of evidence to the contrary, those that do so will be considered to have additive toxic effects.

(d) In establishing tolerances for color additives, the Commissioner will take into consideration, among other things, the amount of any common component permitted in other color additives, in food additives, and in pesticide chemical residues as well as the similar biological activity (such as

cholinesterase inhibition) produced by such substance.

### § 70.19 Fees for listing.

(a) Each petition for the listing of a color additive shall be accompanied by a deposit of \$3,000.00 if the proposal is for listing the color additive for use generally in or on foods, in or on drugs, and in or on cosmetics.

(b) If the petition for the listing is for use in or on foods only, the deposit shall be \$3,000.00.

(c) If the petition for the listing is for use in or on drugs and/or cosmetics only, the deposit shall be \$2,600.00.

(d) The provisions of paragraphs (a), (b), and (c) of this section shall be applicable, whether or not the proposal contemplates any tolerances, limitations, or other restrictions placed upon the use of the color additive.

(e) If a petition proposing the issuance of a regulation is withdrawn before it is finally accepted for filing, the deposit, less a \$600.00 fee for clerical handling and administrative and technical review, shall be returned to the petitioner.

(f) If a petition proposing the issuance of a regulation is withdrawn within 30 days after filing, the deposit, less \$1,800.00 if the petition is covered by paragraph (a) or (b) of this section, and less \$1,600.00, if the petition is covered by paragraph (c) of this section, shall be returned to the petitioner.

(g) When a petition is withdrawn after filing and resubmitted within 6 months, it shall be accompanied by a deposit of \$1,800.00 for a petition filed under paragraph (a) or (b) of this section, and \$1,600.00 for a petition filed under paragraph (c) of this section. If a petition is resubmitted after 6 months, it shall be accompanied by the deposit that would be required if it were being submitted for the first time.

(h) When the resubmission pertains to a petition that had been withdrawn before acceptance for filing, a new advance deposit shall be made in full as prescribed in paragraph (a), (b), or (c) of this section.

(i) After a color additive has been listed, any request for an amendment or additional tolerance shall be accompanied by a deposit of \$1,800.00 for use in the items specified in paragraphs (a)